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Re: Patent Term Extension
Application for
U.S. Patent No. Re 32,969

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 32,969 reissued June 27, 1989, which claims the medical device Orcolon, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 931 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 12, 1991. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1,141) + 410 \\ &= 981 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c) (3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (March 29, 1991) when added to the period of extension calculated above (981 days) cannot exceed fourteen years. The period of extension is thus limited to March 29, 2005, by operation of 35 USC § 156 (c) (3). Since the patent term of seventeen years (35 USC § 154) would expire on September 10, 2002, the period of extension is the number of days to extend the term of the patent from its expiration date to and including March 29, 2005, or 931 days.

The limitations of 35 USC § 156 (g) (6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. Re. 32,969 a certificate of extension, under seal, for a period of 931 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	Re. 32,969
Reissued:	June 27, 1989
Applicant:	Seymour F. Trager et al
Owner of Record:	Seymour F. Trager et al
Title:	INJECTIONABLE VISCOELASTIC OPHTHALMIC GEL
Classification:	424/81
Product Trade Name:	Orcolon
Term Extended:	931 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Orcolon
FDA Docket No.: 91E - 0226